

REMARKS

I. Status of Claims

Claims 1-5, 12-14, 17, 20-26, and 36-39 are pending following entry of this Amendment. Applicants have canceled claims 40-53. In addition, Applicants have amended claims 1, 17, 20, and 23 to more clearly describe the organization of the promoter, IRES elements, and cistrons. Support for this amendment can be found throughout the specification and original claims. In particular, support can be found in the specification in the last paragraph of page 17 and the first paragraph of page 18, and in the organization of the vectors described in the Examples, as summarized in Table 1 on page 34 and Table 2 on page 37. This amendment adds no new matter.

Applicants have also amended claims 1, 17, 20, and 23 to recite the nucleotide sequences comprising the IRES previously recited in canceled claims 40-52. As noted in the response filed March 18, 2005, this subject matter finds support throughout the specification and original claims, but especially on page 17 and in Table 2 of the specification, and in Examples 6 to 9. This amendment adds no new matter.

Claims 1, 17, 20 and 23 also now recite that the nucleotide sequence that provides IRES activity can be a nucleotide sequence that differs from a nucleotide sequence comprising SEQ ID NO. 2 by substitution of the nucleotides at positions 126-129 of SEQ ID NO. 2. Support for this amendment can be found in the specification on page 38, where the specification identifies not only nucleotides 136-139 of homeobox A1 as a potential PTB-binding site, but also nucleotides 126-129. This amendment adds no new matter.

Applicants again note that claims 36-39 are process claims which depend from elected product claims. Upon finding the product claims allowable, Applicants respectfully request that the Office rejoin and fully examine method claims 36-69, as required by rejoinder practice under M.P.E.P. § 821.04. Claims 1-5, 12-14, 17, and 20-26 are under consideration.

II. Rejections Under 35 U.S.C. § 112-1, Enablement

A. “Variants” and “Fragments”

In the Office Action mailed July 15, 2005, the Office rejects claims 1-5, 12-14, 17, 20-26 and 53 under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not enabled by the specification. Office Action, page 4. While acknowledging that the specification enables vectors comprising certain nucleotide sequences, *id.* at 4-5, the Office maintains its position that “variants,” such as nucleotide sequences 80% or 90% identical to SEQ ID NO. 1, and “fragments” are not enabled by the specification, *id.* at 6-7.

Applicants traverse those rejections for essentially the same reasons as set forth in the response filed March 18, 2005. However, solely to expedite prosecution, Applicants have amended claims 1, 17, 20 and 23 to recite the subject matter the Office acknowledges is enabled by the specification. In addition, Applicants respectfully submit that a nucleotide sequence differing from a nucleotide sequence comprising SEQ ID NO. 2 by substitution of the nucleotides at positions 126-129 of SEQ ID NO. 2 is also enabled by the specification. The specification on page 38 identifies not only nucleotides 136-139 of homeobox A1 as a potential PTB-binding site, but also

nucleotides 126-129. Applicants have therefore included this nucleotide sequence in the amendment to claims 1, 17, 20 and 23. Claim 53 has been canceled. Applicants respectfully submit these amendments obviate the rejection of record under 35 U.S.C. § 112, first paragraph, with respect to “variants” and “fragments.”

B. Arrangement of IRES and cistrons

The Office also newly rejects claims 1-5, 12-14, 17, 20-26 and 40-53 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for all possible arrangements of IRESes and cistrons recited in the claims. Office Action, pages 8-10. According to the Office, the intended arrangement as described in the specification is promoter-cistron1-IRES-cistron2, but the claims encompass other arrangements that would not lead to the expression of protein. *Id.* at 10.

Applicants respectfully submit that the skilled artisan would understand from the disclosure which arrangements result in translation of the cistrons so that no undue experimentation would be required to practice the claimed invention. Nevertheless, Applicants have amended claims 1, 17, 20 and 23 to clarify that a nucleotide sequence that provides IRES activity is operably linked to each cistron subsequent to the first cistron. As noted by the Office, this arrangement of vector elements is supported throughout the specification. For example, the last paragraph of page 17 and the first paragraph of page 18 describe the organization of the vector elements generally, and Table 1 on page 34 and Table 2 on page 37 summarize specific examples disclosed in the specification. In addition, Applicants have canceled claims 40-53. Applicants respectfully submit this amendment obviates the rejection.

III. Rejections Under 35 U.S.C. § 112-1, Written Description

The Office also rejects claims 1-5, 12-14, 17, 20-26 and 53 under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description. Office Action, page 11. The Office asserts that the claims lack adequate written description for essentially the same reasons as set forth in the scope of enablement rejection. *Id.* Applicants respectfully submit that the amendments to the claims obviate the written description for the same reasons that they obviate the scope of enablement rejection. Accordingly, Applicants request that the Office withdraw it.

IV. Rejection Under 35 U.S.C. § 102(b)

According to the Office, claims 40, 41, 43 and 45 are anticipated under 35 U.S.C. § 102(b) by Mlodzik et al., EMBO J., Vol. 7, pp. 2569-78 (1988), as evidence by Technical Services, Promega Catalog, NCBI printout for GI: 58196 (1993). Office Action, page 12.

Applicants have canceled claims 40, 41, 43 and 45. The rejection is therefore moot and the Office should withdraw it.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge
any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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